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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/049,464	06/18/2002	Thomas Huenig	ALBRE 23	3876

23599 7590 12/09/2004

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EXAMINER
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OUSPENSKI, ILIA I

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/049,464	<b>Applicant(s)</b> HUENIG, THOMAS	
	<b>Examiner</b> ILIA OUSPENSKI	<b>Art Unit</b> 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 13 February 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 1-5 and 16-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 6-15 are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicant's Preliminary Amendment, filed 02/13/2002, is acknowledged.

Claims 3 – 5, 8 – 11, 14 – 15, and 18 have been amended.

Claims 1 – 18 are pending.

2. Claims 1 – 5 and 16 – 18 are withdrawn from consideration by the Examiner as drawn to non-statutory subject matter. "Application" claims are non-statutory under 35 U.S.C. 101 because the claimed recitation of an application, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example Ex parte Dunki, 153 USPQ 678 (Bd. App. 1967) and Clinical Products, Ltd v. Brenner, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). See MPEP 2173.05(q).

*Claims 6 – 15 are under consideration in the instant application.*

### ***Election/Restrictions***

In the interest of compact prosecution the following is noted:

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

4. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

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Group I, claims 6 – 11, drawn to a pharmaceutical composition containing an anti-CD28 antibody and one or two reverse transcriptase inhibitors and one or two protease inhibitors.

Group II, claims 12 – 15, drawn to a method for treating virus infections with a composition containing an anti-CD28 antibody and one or two reverse transcriptase inhibitors and one or two protease inhibitors.

5. The inventions listed as Groups I - II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The invention of Group I was found to have no special technical feature that defined the contribution over the prior art of Dagan (US Pat. No. 6,146,629; see entire document).

Dagan teaches pharmaceutical compositions comprising a monoclonal antibody and an anti-viral agent (claim 6).

Since Applicant's inventions do not contribute a special technical feature when viewed over the prior art they do not have a single general inventive concept and so lack unity of invention.

### ***Species Election***

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

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Reverse transcriptase inhibitors:

- A. AZT (zidovudine),
- B. 3TC (lamivudine),
- C. 4dT (stavudine),
- D. dd1 (didanosine),
- E. ddC (delavirdine), or
- F. NVP (nevirapine).

Protease inhibitors:

- G. IDV (indinavir),
- E. NFV (nelfinavir),
- H. RTV (ritonavir), or
- I. SQV (saquinavir).

Applicant is required under 35 USC 121 to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable, wherein the species is a composition comprising one or two reverse transcriptase inhibitors from A – F above and, optionally, one or two protease inhibitors from G – I above.

7. It is noted that claims 6 and 12 include a recitation of an antibody to CD28 or “an analogue thereto,” whereas the specification discloses at least on page 10 that analogues can be synthetic proteins, RNA or DNA. In the event that specific embodiments of “analogues” are introduced into the claims during prosecution, additional restriction will be required.

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8. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

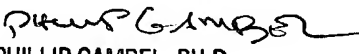
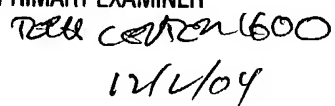
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI

Patent Examiner

Art Unit 1644

November 23, 2004

  
PHILLIP GAMBEL, PH.D  
PRIMARY EXAMINER  
  
12/4/04